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COMPARATIVE ANALYSIS OF REGULATORY PATHWAY OF CLASS C (INFUSION PUMP) AND CLASS D (PACEMAKER) MEDICAL DEVICES IN INDIA WITH CLASS II (INFUSION PUMP) AND CLASS III (PACEMAKER) MEDICAL DEVICES IN THE USA

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ABSTRACT
Objectives: To compare the approval process of selected medical devices—Class C (infusion pump), and Class D (pacemaker) in India and in the United States.
Methods: A comparative review of regulatory frameworks was conducted using the Medical Devices Rules, 2017 under the Central Drugs Standard Control Organization (CDSCO) and the device classification system of the U.S. Food and Drug Administration (FDA). Data were analyzed based on risk classification, licensing procedures, conformity assessment, and premarket requirements.
Results: Medical Devices in India are categorised into Classes A (low risk) to D (high risk). Class C devices (infusion pumps) and Class D devices (pacemakers) undergo stringent evaluation, including clinical evidence and approval by the Central Licensing Authority. Approval process in India requires online CDSCO submission, technical dossiers, ISO 13485 compliance, fees ranging from ₹5,000 to ₹50,000 per application, and review timeframes of 6 to 9 months. In the United States, the FDA classifies them into Class I–III; Class II devices like infusion pumps generally follow the 510(k)-pathway, demonstrating substantial equivalence, whereas Class III devices, such as pacemakers, require Premarket Approval (PMA) supported by extensive clinical data. In the USA, Class II and III devices must go through the PMA or 510(k) processes, which can cost up to US$ 540,783, entail extensive safety, performance, and clinical data investigations, and take 3 to 12 months to approve.
Conclusion: Both countries adopt risk-based frameworks with increasing regulatory rigor for higher-risk devices. However, the U.S. emphasizes the requirements of Pre- Market Approval, while India relies on CDSCO licensing and conformity assessments.

KEYWORDS: Infusion pump, Pacemaker, Medical Devices, CDSCO, USFDA.

INTRODUCTION

The pharmaceutical industries are expanding rapidly, and as regulatory affairs play a significant role in the pharmaceutical industry, the need for regulatory affairs specialists to meet the current needs of businesses for the global competition is also increasing. A regulatory affairs professional serves as the source of link between the pharmaceutical industry and international governing bodies like the Central Drug Standard Control Organization (CDSCO), the U.S. Food and Drug Administration (US FDA), Health Canada, Therapeutic Goods Administration (TGA), etc.[1]

A medical device is defined as any instrument, device utilize machine, implant, chemical agent for in-vitro use, software, material or other related or related article, knowing by the manufacturer to be used, alone or in collection for human beings, for one or more of the specific medical purposes of diagnosis, prevention, monitoring, treatment of diseases.[2] The growing population will drive the demand for healthcare services, and this activity will change the demand for medical devices in India.[2] The chronic diseases will drive the demand for health care services with basic and advanced medical devices and technology.[3]

The healthcare and medical devices aspect in India has grown significantly over the last few years. A wide range of medical devices, from expendable to implantable, is produced in India. The number of medical devices manufactured in India includes items such as catheters, perfusion sets, extension lines, cannulas, feeding tubes, needles, and syringes, as well as implants such as cardiac stents, drug-eluting stents, intraocular lenses, and orthopaedic implants. Medical devices play a major role in the treatment and cure of diseases. They help outpatients to lead normal lives, like physiotherapy treatment centres. The Indian medical device industry is growing at a commendable rate due to its large potential in healthcare. Medical devices have improved physicians' ability to analyse and treat diseases, making great strides in health care and improving the quality of life. In India, the growth of the medical devices market is estimated at 10-15 per cent.[4]

The regulatory process for the CE mark is rather simple. It involves following the Medical Device Directive (93/42/EEC) to identify the conformity assessment procedures for that particular product. For Class III devices (implantable devices, which require the highest assurance of safety and effectiveness before they can be used in a clinical setting).[5]

The USA is currently the largest medical device market globally, followed by the EU and Australia, with Japan ranking fourth.[6]

The Japanese market is poised for further expansion, particularly with the ageing population projected to increase from 28% in 2020 to 38% by 2065.[8] Additionally, North America is expected to lead the global medical device market in terms of revenue until 2026, holding approximately 35% of the market share.[9] This dominance is driven by factors such as the presence of key players, expanding healthcare infrastructure, rapid adoption of advanced medical technologies and a favourable regulatory framework. Meanwhile, in 2026, Europe is forecasted to experience the highest compound annual growth rate, supported by its well-established healthcare system and increasing adoption of advanced diagnostic and treatment devices.[6]

METHODOLOGY

Regulatory Pathway for approval of Infusion Pump and Pacemaker in India

In India, medical devices are categorised into Classes A to D based on risk level. The infusion pump falls into class II, and the pacemaker belongs to class D. The research focuses on the approval process for moderate- and high-risk medical devices in India and the USA. CDSCO is the primary regulatory body for medical device approval in India, whereas the US FDA is the regulatory body for medical device approval in the USA. In the USA, an infusion pump is classified as class II, and a pacemaker is classified as class III. CDSCO and USFDA guidelines are used to compare the approval processes for medical devices across device classes, risk categorisation, manufacturing premises inspections, labelling requirements, timelines, and fees.

Flow Chart for the Approval of Medical Devices

General Data
↓
Device Details → Intended Use
↓
Device Classification
Class A → B → C → D
↓
Regulations
Medical Devices Rules, 2017
↓
Document Necessity
↓
Registration Process
CDSCO Online Portal → Import/Manufacturing License
↓
Timeline
3–6 months
↓
Fees

Regulatory pathway for class II medical device Infusion Pump in the USA:

Flow Chart of the Approval Process of Class II Medical Device

General Data
↓
Device description → Intended use
↓
Device Classification
Class I → Class II → Class III
↓
Regulations
FD&C Act → 21 CFR → FDA Guidance
↓
Document Necessity
↓
Registration Process
Establishment Registration → Device Listing → 510(k) / PMA / Exemption
↓

Timeline
Class I: Immediate | Class II: 3–6 months | Class III: 6–12 months
↓
Fees
Moderate to High (User Fees)

Flow Chart of the Approval Process of Class III Medical Device
General Data
↓
Device description → Intended use
↓
Device Classification
Class I → Class II → Class III
↓
Regulations
FD&C Act → 21 CFR → FDA Guidance
↓
Document Necessity
↓
Registration Process
Establishment Registration → Device Listing → 510(k) / PMA /Clinical Investigations/ IDE
↓
Timeline
Class I: Immediate | Class II: 3–6 months | Class III: 6–12 months
↓
Fees
Moderate to High

RESULTS AND KEY FINDINGS
The comparative analysis of the Regulatory Pathway of Medical Devices showed that both India and the United States follow a risk-based classification system, where infusion pumps are categorised as moderate to high-risk devices (Class C in India and Class II in the U.S.), while pacemakers are classified as high-risk devices (Class D in India and Class III in the U.S.).
In India, the regulatory pathway is governed by the Central Drugs Standard Control Organisation under the Medical Devices Rules, 2017, requiring licensing, technical documentation, and quality management compliance, whereas in the United States, the U.S. Food and Drug Administration regulate devices through pathways such as 510(k) clearance for Class II devices and Premarket Approval (PMA) for Class III devices.
The study further indicated that pacemakers undergo more stringent approval and clinical evaluation requirements than infusion pumps in both countries, due to their life-supporting, implantable nature, reflecting the increasing regulatory controls associated with higher device risk classifications. The evaluation data is presented in the following Table.1

Table 1. Comparative evaluation of CDSCO and the USA approval process Infusion Pump:

S. No	Parameter	INDIA	USA	Key Observations
1	**Definition**	As per the Drugs and Cosmetics Act 1940 and MDR 2020, all devices, including an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including software or an accessory, intended by its manufacturer to be used specially for human beings or animals.	The FDA defines a medical device as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part or accessory, which is: recognised in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them.	Both agencies defined medical devices similarly.
2	**Regulatory Body**	**CDSCO - DCGI**	**FDA- CDRH**	Different Body
3	**Device Class**	**Class C**	**Class II**	Different Class
4	**Risk**	**Medium to High**	**Medium Risk**	Risk category is same

5	**Approval/ Registration Process**	Manufacturers and importers must follow a multi-step process: • Registering on the CDSCO's **SUGAM portal.** • Submitting an application to the **Central Licensing Authority**, Form **MD-7** for a **manufacturing license.** • Submitting an application to the **Central Licensing Authority**, **Form MD-8** for a **loan license.** Preparing and submitting required documentation, paying fees, and potentially appointing an Indian Authorised Agent.	Registration and listing information is submitted by using FDA's Unified Registration and Listing System **(FURLS)/ Device Registration and Listing Module (DRLM).** Four categories of parties must submit a 510(k) to the FDA: • Domestic manufacturers introducing a device to the U.S. market; • Specification developers introducing a device to the U.S. market • Repackers or relabelers • Foreign manufacturers/exporters **CDRH** Reviewed the Application by **third-party review.** **510(k) Decision Letter** The FDA's goal to make an MDUFA Decision for a 510(k) is **90 FDA Days**.	Both countries having different approval process.
6	**Time Line**	License/Loan License to Manufacture for Sale or for Distribution of Class C medical device Infusion Pump **(MD-9)/(MD-10):** • Completion of scrutiny from the date of online submission of application **45** • Inspection of manufacturing premises from the date of application **60** • Grant of license from the date of receipt of Inspection report By **CLA** **45**	The FDA approval timeline for Class II medical device **Infusion Pump** in the US, using the 510(k) pathway, typically takes **between 3 - 9 months.** While the FDA has a **90-day review period,** additional information requests or other factors can extend this timeframe.	Both countries are having different Timelines process.
7	**Fees**	**Rule-21(2) Manufacturing licence or loan licence** to manufacture Class C medical device Infusion Pump for,- (a) one site; and **50000/-** (b) each distinct medical device. **1000/-** **Rule-34(2) Import licence** for Class C medical device Infusion pump medical device for, - (a) one site; and **$3000** (b) each distinct medical device. **$1500**	**Establishment Registration Fee:** • This is an annual fee that must be paid by all medical device manufacturers and importers. • The fee for **FY 2025 is $9,280** Other fees for Fiscal Year 2025 (October 1, 2024, through September 30, 2025) are: **510(k)‡ $24,335** (Standard Fee) **$6,084** (Small Business Fee†)	Both countries are having different Timelines process

Pacemaker

Sl. No	Parameter	INDIA	USA	Key Observations
1	**Definition**	As per drugs and cosmetic act 1940 and MDR 2020 all devices including an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human beings or animals.	The FDA defines a medical device an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part or accessory which is: recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them.	Both agencies defined medical devices similarly.
2	**Regulatory Body**	**CDSCO - DCGI**	**FDA- CDRH**	Different Body
3	**Device Class**	**Class D**	**Class III**	Different Class
4	**Risk**	**High Risk**	**High Risk**	Risk category is same
5	**Approval/ Registration Process**	To register a Class D medical device **Pacemaker** in India, follow these steps: • Appoint an Indian Authorized Agent. • Submit an application through the **SUGAM Portal**. • Prepare the necessary documentation, including the Device Master File **(DMF),** Plant Master File **(PMF)**, and other supporting documents. • Pay the required fee and submit the application. The Central Drugs Standard Control Organisation (CDSCO) will review the application and may conduct inspections. If approved, will receive the necessary licenses and certificates.	**Premarket Approval (PMA)** application is a scientific, regulatory documentation to FDA to demonstrate the safety and effectiveness of the Class III device **Pacemaker** through **Clinical Investigation.** **Steps:** • Investigational Device Exemption **(IDE)** • Good Clinical Practices **(GCP)** • IDE Approval Process • Institutional Review Board **(IRB)** • Approval Order	Both countries are having different approval process.
6	**Time Line**	License/Loan License to Manufacture for Sale or for Distribution of Class D medical device **Pacemaker (MD-9)/(MD-10):** • Completion of scrutiny from the date of online submission of application **45** • Inspection of manufacturing premises from the date of application **60** • Grant of license from the date of receipt of Inspection report By **CLA.** **45**	**FDA** Approval Timeline for Class III device **Pacemaker,** which pose a higher risk, generally follow the **Premarket Approval (PMA)** process, which typically takes **at least 180 days.**	Both countries are having different Timelines process.
7	**Fees**	**Rule-21(2) Manufacturing licence or loan licence** to manufacture Class D medical device **Pacemaker** for,- (a) one site; and **50000/-** (b) each distinct medical device. **1000/-** **Rule-34(2) Import licence** for Class D medical device **Pacemaker** for, -	**Establishment Registration Fee:** • This is an annual fee that must be paid by all medical device manufacturers and importers.	Both countries are having different Timelines process

		(a) one site; and **$3000** (b) each distinct medical device. **$1500**	• The fee for **FY 2025 is $9,280** Other fees for Fiscal Year 2025 (October 1, 2024, through September 30, 2025) are: PMA, PDP, PMR, BLA **$540,783** (Standard Fee) **$135,196**(Small Business Fee†)	

DISCUSSION

Medical devices are essential equipment in the health sector. These devices are used to diagnose, treat, prevent or mitigate medical conditions. Their complexity can vary based on their function and purpose, the technology involved, their interaction with the human body and the associated risk. These products undergo a very demanding development process to ensure the final device meets the desired standards for safety, efficacy and quality[7].

Regulatory Pathway of medical devices into the regulatory regime ensures that only safe, effective, and good quality devices reach the market. The pathways vary in complexity based on the risk classification of these medical devices[8].

In India, medical devices are regulated by the Central Drugs Standard Control Organization under the Medical Devices Rules, 2017. Class C infusion pumps require licensing supported by technical documentation, quality management system compliance, and performance data. Class D pacemakers undergo more rigorous evaluation, requiring detailed evidence of safety, efficacy, and clinical performance. Compliance with ISO 13485 and review by the Central Licensing Authority are essential components of the approval process[9].

In the United States, regulation is overseen by the U.S. Food and Drug Administration. Infusion pumps are generally classified as Class II devices and are approved through the 510(k) pathway, which requires demonstration of substantial equivalence to a predicate device. This process is generally faster and less resource-intensive. Pacemakers, classified as Class III devices, require Premarket Approval (PMA), involving extensive preclinical studies, clinical trials, manufacturing assessments, and comprehensive safety and effectiveness data[10].

In Australia, the Therapeutic Goods Administration (TGA) regulates medical devices. The process includes device classification, appointing an Australian sponsor, obtaining a conformity assessment certificate, preparing technical documentation, applying for ARTG inclusion, and undergoing audits. The timeline ranges from 6 months to over 2 years, depending on complexity. Import and export require ARTG listing, permits, documentation, customs clearance, labelling, and record-keeping. Fees are relatively low—AUD $0–$1,000 for imports and AUD $170–$270 for export certificates[11].

In Saudi Arabia, the Saudi Food and Drug Authority (SFDA) oversee approvals. The process involves appointing a Saudi Authorised Representative, preparing the technical file, submitting for MDMA approval, and obtaining establishment/importer licensing. Timelines are shorter (~2–3 months). Import/export requires regulatory registration, customs clearance, and post-market compliance. Fees are higher for high-risk devices—Class D can reach SAR 23,000.

Infusion Pumps are Class IIb Medium-to-high risk active devices. These require a full conformity assessment by a Notified Body, including an audit of the manufacturer's Quality Management System (QMS) and technical documentation.

Pacemakers are Class III Highest risk devices. As active implantable devices, they undergo the most stringent scrutiny. This includes expert panel reviews of clinical data, rigorous Notified Body audits, and mandatory Summary of Safety and Clinical Performance (SSCP) reports.

The present study compared the regulatory pathways of Class C (infusion pump) and Class D (pacemaker) medical devices in India with the corresponding Class II and Class III devices in the United States. Both countries employ a risk-based classification system, ensuring that regulatory controls increase with the potential risk posed by the device. However, notable differences exist in regulatory procedures, approval requirements, review processes, and timelines[12].

CONCLUSION

This study provides a comparative analysis of the regulatory pathways for Class C (infusion pump) and Class D (pacemaker) medical devices in India and their corresponding Class II and Class III devices in the United States. The findings indicate that both countries follow a risk-based classification system, ensuring that regulatory controls increase with the potential risk associated with the device. Despite this common approach, notable differences exist in regulatory requirements, approval pathways, review processes, and timelines.

In India, medical devices are regulated by the Central Drugs Standard Control Organization under the Medical Devices Rules, 2017, with Class C and D devices requiring licensing supported by technical, quality, and clinical documentation. In contrast, the United States, through the U.S. Food and Drug Administration, employs the 510(k) pathway for Class II infusion pumps and the more rigorous Premarket Approval (PMA) process for Class III

pacemakers. The FDA framework provides a highly structured review system with extensive guidance documents and well-established post-market surveillance mechanisms.

Overall, both regulatory systems aim to ensure the safety, quality, and effectiveness of medical devices before market entry. While India has made significant progress in strengthening its regulatory framework and aligning with international standards, the U.S. system remains more mature and comprehensive. Understanding these regulatory similarities and differences is essential for manufacturers seeking global market access, regulatory compliance, and efficient commercialization of medical devices across both jurisdictions.

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